

**Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application.

Claim 1. (Previously presented) A process for preparing a multivesicular liposomal particle composition of pre-determined, uniform size distribution, the process comprising:

- a) providing a first emulsion by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid;
- b) mixing and emulsifying said first emulsion and a second aqueous phase to provide a second emulsion, said second emulsion comprising a continuous aqueous phase;
- c) sparging the volatile water-immiscible solvent from the second emulsion to form a composition of multivesicular liposomal particles, wherein the sparging comprises at least two steps having different gas flow rates; and
- d) filtering the multivesicular liposomal particle composition by cross-flow filtration.

Claim 2. (Previously presented) The process of claim 1, wherein at least one mixing step is carried out in a mixer selected from the group consisting of dynamic and static.

Claim 3. (Previously presented) The process of claim 2, wherein the static mixer is selected from the group consisting of Kenics and Koch.

Claim 4. (Original) The process of claim 3, wherein the first emulsion and second aqueous solution are passed through the mixer at a linear velocity of from about 100 cm/min to about 500 cm/min.

Claim 5. (Original) The process of claim 1, wherein the volume ratio of the first aqueous phase to the water-immiscible solvent phase is from about 0.33 to about 1.6.

Claim 6. (Previously presented) The process of claim 1, wherein the volume ratio of the first emulsion to the second aqueous phase is from about 0.01 to about 0.5.

Claim 7. (Currently amended) The process of claim 1, wherein the at least one amphipathic lipid is selected from the group consisting of phosphatidylcholines, phosphatidylethanolamines, sphingomyelins, lysophosphatidylcholines, lysophosphatidylethanolamines, ~~are~~ phosphatidylglycerols, phosphatidylserines, phosphatidylinositols, phosphatidic acids, cardiolipins, acyl trimethylammonium propane, diacyl dimethylammonium propane, stearylamine, and ethyl phosphatidylcholine.

Claim 8. (Original) The process of claim 1, wherein the at least one neutral lipid is selected from the group consisting of glycerol esters, glycol esters, tocopherol esters, sterol esters, alkanes and squalenes.

Claim 9. (Original) The process of claim 1, wherein the second aqueous phase further comprises at least one sugar.

Claim 10. (Original) The process of claim 1, wherein the second aqueous phase further comprises at least one amino acid.

Claim 11. (Canceled)

Claim 12. (Previously presented) The process of claim 1, wherein the filtering comprises:

- a) a first concentration of the multivesicular liposomal particle composition, resulting in a concentration increase of from 2-6 times; and
- b) a buffer exchange, resulting in a pH of the multivesicular liposomal particle composition of between about 5 and about 8.

Claim 13. (Original) The process of claim 12, further comprising a second concentration step.

Claim 14. (Previously presented) The process of claim 12, wherein the filtering is carried out with a hollow fiber filter.

Claim 15. (Previously presented) The process of claim 14, wherein the filtering is conducted at a transmembrane pressure of from about 0.1 psi to about 7 psi.

Claim 16. (Previously presented) The process of claim 1, wherein the filtering further comprises back pulsing with a back pulse volume and a retentate back pressure.

Claim 17. (Original) The process of claim 16, wherein the back pulsing is periodic.

Claim 18. (Currently amended) The process of claim 17, wherein the back pulsing ~~step~~ occurs from about every 0.5 minutes to about every 10 minutes.

Claim 19. (Currently amended) The process of claim 18, wherein the back pulsing ~~step~~ occurs from about every 1 minute to about every 5 minutes.

Claim 20. (Previously presented) The process of claim 16, wherein the back pulse volume is from about 0.01% to about 5% of initial filtration volume.

Claim 21. (Currently amended) The process of claim 20, wherein the back ~~pulsing~~ pulse volume is from about 0.01% to about 1.0% of initial filtration volume.

Claim 22. (Previously presented) The process of claim 16, wherein the filtering is conducted at a retentate back pressure of from about 0 psi to about 10 psi.

Claim 23. (Original) The process of claim 1, further comprising potency adjustment of the multivesicular liposomal particle composition.

Claim 24. (Previously presented) The process of claim 23, wherein the potency adjustment is carried out by secondary filtration.

Claim 25. (Original) The process of claim 23, wherein the potency adjustment is carried out by decanting the multivesicular liposomal particle composition.

Claim 26. (Previously presented) The process of claim 1, wherein mixing of the first emulsion is performed using impeller at a speed of from about 2,000 rpm to about 16,000 rpm.

Claim 27. (Currently amended) The process of claim 26, wherein the mixing of the first emulsion is from about 5 minutes to about 100 minutes.

Claim 28. (Previously presented) The process of claim 1, wherein a first sparging step has an inert gas flow rate that is less than that of a second step.

Claim 29. (Previously presented) The process of claim 28, wherein the gas flow rate of the first sparging step is less than about 500 lpm.

Claim 30. (Currently amended) The process of claim 29, wherein the first sparging step has a duration of from about 3 minutes to about 30 minutes.

Claim 31. (Previously presented) The process of claim 29, wherein the gas flow rate of the second sparging step is at least about 700 lpm.

Claim 32. (Currently amended) The process of claim 31, wherein the second sparging step has a duration of from about 2 minutes to about 10 minutes.

Claim 33. (Original) The process of claim 1, wherein the first aqueous phase comprises a physiologically active substance, and the multivesicular liposomal particle composition comprises an encapsulated physiologically active substance.

Claim 34. (Original) The process of claim 33, wherein the physiologically active substance is selected from the group consisting of antianginas, antiarrhythmics,

antiasthmatic agents, antibiotics, antidiabetics, antifungals, antihistamines, antihypertensives, antiparasitics, antineoplastics, antitumor drugs, antivirals, cardiac glycosides, hormones, immunomodulators, monoclonal antibodies, neurotransmitters, nucleic acids, proteins, radio contrast agents, radionuclides, sedatives, analgesics, steroids, tranquilizers, vaccines, vasopressors, anesthetics, peptides, prodrugs and pharmaceutically acceptable salts of the same.

Claim 35. (Currently amended) The process of claim 34, wherein the physiologically active substance is selected from the group consisting of cytarabine, insulin, paclitaxel, 5-flourouracil, floxuridine, morphine, hydromorphone, dexamethasone, methotrexate, bleomycin, vincristine, vinblastine, IgF-1, bupivacaine and amikacin.

Claims 36-48. (Canceled)

Claim 49. (Previously presented) A process for preparing a multivesicular liposomal particle composition of pre-determined, uniform size distribution, the process comprising:

- a) providing a first emulsion by mixing a first aqueous phase and a volatile water-immiscible solvent phase having a volume fraction from about 0.33 to about 1.6, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid;
- b) providing a second emulsion comprising a continuous aqueous phase by mixing and emulsifying said first emulsion and a second aqueous phase having a volume fraction from about 0.01 to about 0.5;
- c) sparging the volatile water-immiscible solvent from the second emulsion to form a composition of multivesicular liposomal particles; and
- d) filtering the multivesicular liposomal particle composition by cross-flow filtration.

Claim 50. (Canceled)

Claim 51. (Original) The process of claim 23, wherein the volume of multivesicular liposomal particle composition is pooled and further processed by multiple batch processing.

Claim 52. (Currently amended) The process of claim 33, wherein the encapsulation efficiency of the physiologically active substance is at least about 67.8%.

Claim 53. (Previously presented) The process of claim 1, wherein the mean particle size before cross-flow filtration is within about 1 micron of the mean particle size after cross-flow filtration.

Claim 54. (Canceled)

Claim 55. (Currently amended) The process of claim 49, wherein the mixing is performed using impeller at a speed of from about 2,000 rpm to about 16,000 rpm.[[.]]

Claim 56. (Currently amended) The process of claim 55, wherein the mixing has a duration of from about 5 min[[.]] to about 100 min.

Claim 57. (Previously presented) The process of claim 49, wherein at least one mixing step is carried out in a static mixer.

Claim 58. (Previously presented) The process of claim 57, wherein the first emulsion and the second aqueous solution are passed through the static mixer at a linear velocity of from about 100 cm/min to about 500 cm/min.

Claim 59. (Previously presented) The process of claim 49, wherein the sparging comprises at least two steps having different gas flow rates.

Claim 60. (Previously presented) The process of claim 59, wherein the gas flow rate of the first sparging step is less than about 500 lpm.

Claim 61. (Previously presented) The process of claim 59, wherein the gas flow rate of the second sparging step is at least about 700 lpm.

Claim 62. (Previously presented) The process of claim 59 wherein the gas flow rate of a further sparging step is less than about 400 lpm.

Claim 63. (Currently amended) A process for preparing a multivesicular liposomal particle composition of pre-determined, uniform size distribution, the process comprising:

- a) providing a first emulsion by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid, using impeller speeds of from about 2,000 rpm to about 16,000 rpm for about 5 minutes to about 100 minutes;

- b) providing a second emulsion by mixing and emulsifying said first emulsion and a second aqueous phase, said second emulsion comprising a continuous aqueous phase;

- c) removing the volatile water-immiscible solvent from the second emulsion to form a composition of multivesicular liposomal particles; and

- d) filtering the multivesicular liposomal particle composition by cross-flow filtration.

Claim 64. (Previously presented) A process for preparing a multivesicular liposomal particle composition, the process comprising:

- a) providing a first emulsion by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid;

- b) providing a second emulsion comprising a continuous aqueous phase by passing said first emulsion and a second aqueous phase through a static mixer at a linear velocity of from about 100 cm/min. to about 500 cm/min;

- c) removing the volatile water-immiscible solvent from the second emulsion to form a composition of drug-containing multivesicular liposomal; and

d) filtering the multivesicular liposomal particle composition by cross-flow filtration.

Claim 65. (Previously presented) A process for preparing a multivesicular liposomal particle composition, the process comprising:

a) providing a first emulsion phase having a volume fraction of from about 0.33 to about 1.6 by mixing a first aqueous phase and a volatile water-immiscible solvent, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid;

b) mixing and emulsifying said first emulsion and a second aqueous phase to provide a second emulsion having a volume fraction of from about 0.01 to about 0.5, said second emulsion comprising a continuous aqueous phase;

c) sparging the volatile water-immiscible solvent from the second emulsion to form a composition of multivesicular liposomal particles of pre-determined, uniform size distribution, wherein the sparging comprises at least two steps having different gas flow rates; and

d) filtering the multivesicular liposomal particle composition by cross-flow filtration.

Claim 66. (Currently amended) A process for preparing a multivesicular liposomal particle composition, the process comprising:

a) providing a first emulsion by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid, wherein the mixing is performed using impeller at a speed of from about 2,000 rpm to about 16,000 rpm;

b) mixing and emulsifying said first emulsion and a second aqueous phase to provide a second emulsion, said second emulsion comprising a continuous aqueous phase;

c) sparging the volatile water-immiscible solvent from the second emulsion to form a composition of multivesicular liposomal particles of pre-determined, uniform size distribution wherein the sparging comprises at least two steps having different gas flow rates; and



d) filtering the multivesicular liposomal particle composition by cross-flow filtration.

Claim 67. (Previously presented) A process for preparing a multivesicular liposomal particle composition, the process comprising:

a) providing a first emulsion by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid;

b) mixing and emulsifying said first emulsion and a second aqueous phase to provide a second emulsion, said second emulsion comprising a continuous aqueous phase wherein the first emulsion and the second aqueous phase are passed through a static mixer at a linear velocity of from about 100 cm/min to about 500 cm/min;

c) sparging the volatile water-immiscible solvent from the second emulsion to form a composition of multivesicular liposomal particles of pre-determined, uniform size distribution, wherein the sparging comprises at least two steps having different gas flow rates; and

d) filtering the multivesicular liposomal particle composition by cross-flow filtration.

Claim 68. (Currently amended) A process for preparing a multivesicular liposomal particle composition, the process comprising:

a) providing a first emulsion having a volume fraction of from about 0.33 to about 1.6 by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid, wherein said mixing is performed by impeller at a speed of from about 2,000 rpm to about 16,000 rpm;

b) mixing and emulsifying said first emulsion and a second aqueous phase to provide a second emulsion having a volume fraction of from about 0.01 to about 0.5, said second emulsion comprising a continuous aqueous phase, wherein the first emulsion and the second aqueous phase are passed through a static mixer at a linear velocity of from about 100 cm/min[[.]] to about 500 cm/min;

c) sparging the volatile water-immiscible solvent from the second emulsion to form a composition of multivesicular liposomal particles of pre-determined, uniform size distribution; and

d) filtering the multivesicular liposomal particle composition by cross-flow filtration to adjust concentration.

Claim 69. (Previously presented) A process for preparing a multivesicular liposomal particle composition, the process comprising:

a) providing a first emulsion by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid;

b) mixing and emulsifying said first emulsion and a second aqueous phase to provide a second emulsion, said second emulsion comprising a continuous aqueous phase;

c) sparging the volatile water-immiscible solvent from the second emulsion to form a composition of multivesicular liposomal particles of pre-determined, uniform size distribution; wherein the sparging step comprises

(i) a first step having a gas flow rate of less than about 500 lpm; and

(ii) a second step having a gas flow rate of at least 700 lpm; and

d) filtering the multivesicular liposomal particle composition by cross-flow filtration to exchange buffer therein.

Claim 70. (Previously presented) A process for preparing a multivesicular liposomal particle composition, the process comprising:

a) providing a first emulsion by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid;

b) mixing and emulsifying said first emulsion and a second aqueous phase to provide a second emulsion, said second emulsion comprising a continuous aqueous phase;

c) sparging the volatile water-immiscible solvent from the second emulsion to form a composition of multivesicular liposomal particles of pre-determined, uniform size distribution, wherein said sparging comprises

- (i) a first step having a gas flow rate of less than about 500 lpm;
- (ii) a second step having a gas flow rate of at least about 700 lpm; and
- (iii) a third step having a gas flow rate of less than about 300 lpm; and

d) filtering the multivesicular liposomal particle composition by cross-flow filtration.

Claim 71. (Currently amended) A process for preparing a multivesicular liposomal particle composition, the process comprising:

a) providing a first emulsion by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid;

b) mixing and emulsifying said first emulsion and a second aqueous phase to provide a second emulsion, said second emulsion comprising a continuous aqueous phase;

c) sparging the volatile water-immiscible solvent from the second emulsion to form a composition of multivesicular liposomal particles of pre-determined, uniform size distribution, wherein the sparging comprises

(i) a first step having a gas flow rate of less than about 375 lpm for about 3 minutes to about 30 ~~min~~-minutes;

(ii) a second step having a gas flow rate of at least about 1000 lpm for about 2 minutes to about 10 ~~min~~-minutes; and

(iii) a third step having a gas flow rate of less than about 250 lpm for about 2 minutes to about 90 ~~min~~-minutes; and

d) filtering the multivesicular liposomal particle composition by cross-flow filtration.

Claim 72. (Previously presented) A process for preparing a multivesicular liposomal particle composition, the process comprising:

- a) providing a first emulsion having a volume fraction of from about 0.33 to about 1.6 by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid;
- b) mixing and emulsifying said first emulsion and a second aqueous phase to provide a second emulsion having a volume fraction of from about 0.01 to about 0.5, said second emulsion comprising a continuous aqueous phase;
- c) sparging the volatile water-immiscible solvent from the second emulsion to form a composition of multivesicular liposomal particles of pre-determined, uniform size distribution, wherein said sparging comprises
  - (i) a first step having a gas flow rate of at least about 500 lpm;
  - (ii) a second step having a gas flow rate of at least 700 lpm; and
  - (iii) a third step having a gas flow rate of less than about 300 lpm; and
- d) filtering the multivesicular liposomal particle composition by cross-flow.

Claim 73. (Canceled)

Claim 74. (Currently amended) A process for making a multivesicular liposomal composition, the method comprising:

- a) providing a first emulsion having a volume fraction of from about .033 to about 1.6 by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid, wherein said mixing is performed by impeller at a speed of about 2,000 rpm to about 16,000 rpm;
- b) mixing and emulsifying said first emulsion and a second aqueous phase to provide a second emulsion having a volume fraction of from about 0.01 to about 0.5, said second emulsion comprising a continuous aqueous phase, wherein the first emulsion and the second aqueous phase are passed through a static mixer at a linear velocity of from about 100 cm/min[[.]] to about 500 cm/min[[.]];
- c) sparging the volatile water-immiscible solvent from the second emulsion to form a composition of multivesicular liposomal particles of pre-determined, uniform size distribution, wherein the sparging comprises
  - (i) a first step having a gas flow rate of less than about 500 lpm;

- (ii) a second step having a gas flow rate of at least about 700 lpm; and
- (iii) a third step having a gas flow rate of less than about 300 lpm; and
- d) filtering the composition by cross-flow filtration.

Claim 75. (Currently amended) A process for making a multivesicular liposomal composition, the method comprising:

a) providing a first emulsion having a volume fraction of from about 0.33 to about 1.6 by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid, wherein the mixing is performed by impeller at a speed of from about 2,000 rpm to about 16,000 rpm for a duration of from about 5 minutes to about 100 minutes;

b) mixing and emulsifying said first emulsion and a second aqueous phase to provide a second emulsion having a volume fraction of from about 0.01 to about 0.5, said second emulsion comprising a continuous aqueous phase, wherein the first emulsion and the second aqueous phase are passed through a static mixer with a linear velocity of from about 100 cm/min[[.]] to about 500 cm/min;

c) sparging the volatile water-immiscible solvent from the second emulsion to form a composition of multivesicular liposomal particles of pre-determined, uniform size distribution, wherein the sparging comprises

- (i) a first step having a gas flow rate of less than about 375 lpm;
- (ii) a second step having a gas flow rate of at least about 1000 lpm; and
- (iii) a third step having a gas flow rate of less than about 250 lpm; and
- d) filtering the multivesicular liposomal particle composition by cross-flow filtration.

Claim 76. (Currently amended) A process for making a multivesicular liposomal composition, the method comprising:

a) providing a first emulsion having a volume fraction of from about 0.33 to about 1.6 by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid, wherein the mixing is performed by impeller at a velocity of from about 2,000 rpm to about 16,000 rpm for a duration of from about 5 minutes to about 100 minutes;

b) mixing and emulsifying said first emulsion and a second aqueous phase to provide a second emulsion having a volume fraction of from about 0.01 to about 0.5, said second emulsion comprising a continuous aqueous phase, wherein the mixing is performed by impeller at less than about 2,000 rpm for a duration of from about 1 minute to about 10 minutes;

c) sparging the volatile water-immiscible solvent from the second emulsion to form a composition of drug-containing multivesicular liposomal particles of pre-determined, uniform size distribution, wherein the sparging comprises

- (i) a first step having a gas flow rate of about 375 lpm;
- (ii) a second step having a gas flow rate of about 1000 lpm; and
- (iii) a third step having a gas flow rate of about 250 lpm; and

d) filtering the multivesicular liposomal particle composition by cross-flow filtration.

Claim 77. (Currently amended) A method for making a multivesicular liposomal composition, the method comprising:

a) providing a first emulsion having a volume fraction of from about 0.33 to about 1.6 by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid, wherein the mixing is performed by impeller at a speed of from about 2,000 rpm to about 16,000 rpm for a duration of about 5 minutes to about 100 minutes at a temperature of from about 15°C to about 40°C;

b) mixing and emulsifying said first emulsion and a second aqueous phase to provide a second emulsion having a volume fraction of from about 0.01 to about 0.5, said second emulsion comprising a continuous aqueous phase, wherein the mixing is performed by impeller for a duration of about 1 minute to about 10 minutes at a temperature of about 20°C to about 50°C;

c) sparging the volatile water-immiscible solvent from the second emulsion to form a composition of multivesicular liposomal particles of pre-determined, uniform size distribution, wherein the sparging comprises

- (i) a first step having a gas flow rate of less than about 500 lpm; and
- (ii) a second step having a gas flow rate of at least about 700 lpm; and

d) filtering the multivesicular liposomal particle composition by cross-flow filtration.

Claim 78. (Currently amended) A method for making a multivesicular liposomal composition, the method comprising:

a) providing a first emulsion having a volume fraction of from about 0.33 to about 1.6 by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid, wherein said mixing is performed by impeller at a speed of from about 2,000 rpm to about 16,000 rpm, for a duration of from about 5 minutes to about 100 minutes, at a temperature of from about 15°C to about 40°C;

b) mixing and emulsifying said first emulsion and a second aqueous phase to provide a second emulsion having a volume fraction of from about 0.01 to about 0.5, said second emulsion comprising a continuous aqueous phase, wherein the first emulsion and the second aqueous phase are passed through a static mixer at a linear velocity of from about 100 cm/min to about 500 cm/min;

c) sparging the volatile water-immiscible solvent from the second emulsion to form a composition of multivesicular liposomal particles of pre-determined, uniform size distribution, wherein the sparging comprises

- (i) a first step having a gas flow rate of less than about 500 lpm;
- (ii) a second step having a gas flow rate of at least about 700 lpm; and
- (iii) a third step having a gas flow rate of less than about 300 lpm; and

d) filtering the multivesicular liposomal particle composition by cross-flow filtration.

Claim 79. (Currently amended) A method for making a multivesicular liposomal composition, the method comprising:

a) providing a first emulsion having a volume fraction of from about 0.33 to about 1.6 by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid, wherein the mixing is performed by impeller at a speed of from about 2,000 rpm to about

16,000 rpm for a duration of from about 5 minutes to about 100 minutes at a temperature of from about 15°C to about 40°C;

b) mixing and emulsifying said first emulsion and a second aqueous phase to provide a second emulsion having a volume fraction of from about 0.01 to about 0.5, said second emulsion comprising a continuous aqueous phase, wherein the mixing is performed by impeller at a speed of less than about 2,000 rpm for a duration of ~~from~~from about 1 minute to about 10 minutes at a temperature of from about 20°C to about 50°C;

c) sparging the volatile water-immiscible solvent from the second emulsion to form a composition of [[g]] multivesicular liposomal particles of pre-determined, uniform size distribution, wherein the sparging comprises

(i) a first step having a gas flow rate about 375 lpm for about 17 minutes;

(ii) a second step having a gas flow rate of about 1000 lpm for about 5 minutes; and

(iii) a third step having a gas flow rate of about 250 lpm for about 28 minutes; and

d) filtering the multivesicular liposomal particle composition by cross-flow filtration.

Claim 80. (Previously presented) A product produced in accordance with the process of claim 63.

Claim 81 (Previously presented) A product produced in accordance with the process of claim 64.

***Claims 82-83. (Canceled)***

Claim 84. (Previously presented) In a process for preparing a multivesicular liposomal composition comprising a preparation of first and second emulsion steps, and a solvent removal step, the improvement comprising removal of solvent by sparging, wherein the sparging comprises at least two steps having different gas flow rates.



Claim 85. (Previously presented) In a process for preparing a multivesicular liposomal composition comprising preparation of first and second emulsion steps, and a solvent removal step, the improvement comprising the first emulsion having a dispersed phase to continuous phase volume fraction of from about 0.33 to about 1.6.

Claim 86. (Previously presented) In a process for preparing a multivesicular liposomal composition comprising preparation of first and second emulsion steps, and a solvent removal step, the improvement comprising the second emulsion having a first emulsion to second aqueous phase volume fraction of from about 0.01 to about 0.5.

Claim 87. (Currently amended) In a process for preparing a multivesicular liposomal composition comprising preparation of first and second emulsion steps, and a solvent removal step, the improvement comprising mixing the first emulsion using impeller at a speed of from about 2,000 rpm to about 16,000 rpm.

Claim 88. (Previously presented) In a process for preparing a multivesicular liposomal composition comprising preparation of first and second emulsion steps, and a solvent removal step, the improvement comprising passing the first emulsion and second aqueous phase through the static mixer at a linear velocity of from about 100 cm/min to about 500 cm/min.

Claim 89. (Currently amended) In a process for preparing a multivesicular liposomal composition comprising preparation of first and second emulsion steps, and a solvent removal step, the improvement comprising the first emulsion having a dispersed phase to continuous phase volume fraction of from about 0.33 to about 1.6 and being mixed using impeller at a speed of from about 2,000 rpm to about 16,000 rpm for a duration of from about 5 minutes to about 100 minutes, and the second emulsion having a first emulsion to second aqueous phase volume fraction of from about 0.01 to about 0.5 and being mixed in a static mixer at a linear velocity of from about 100 cm/min to about 500 cm/min, and removal of solvent by sparging, wherein the sparging comprises at least two steps having different gas flow rates.